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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,527	05/29/2003	Sean Farmer	19374-503	8102

30623 7590 05/03/2007

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER	
KOSAR, AARON J	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
05/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/424,527	FARMER ET AL.	
	Examiner	Art Unit	
	Aaron J. Kosar	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30-June-2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25, and 51* is/are pending in the application.

4a) Of the above claim(s) *20 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,21-24, and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment and argument filed June 30,2006 in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Currently, claims 1-19, 21-24, and new claim 51 are pending and have been examined on the merits.

During the course of examination, prior art embracing non-elected species, *Lactobacillus sp.*, including *L. acidophilus* has been discovered. Consequently, *L. acidophilus* has been examined in the present Action along with *B. coagulans*, since the simultaneous examination is not unduly burdensome.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 14 claims a polysaccharide with about 4-100 sugar unit chain length. Applicant's original disclosure provides the range 4-200 units, but only provides support in the specification for fructo-oligosaccharides (FOS). Claims to gluco-oligosaccharides (GOS), raffinose-based oligosaccharides, and other long-chain oligosaccharides are not supported by the originally-filed specification.

Claim Objections

Claims 1,3,14,23,24 are objected to because of the following informalities:

In claims 1,3,23,24, the proper taxonomic classification of organisms according to genus-species should be italicized, such as *Clostridium perfringens*. Appropriate correction is required.

In claim 3, *C. sporegenes* appears to be a typographical error of *C. sporogenes*.

In claim 14, the phrase "*oligosaccharide comprises polymers of having a polymer chain length of from about 4 to 100 sugar units*" is awkward. Examiner is treating claim 14 as meaning the claimed oligosaccharide comprises a polysaccharide having a polymer chain length of about 4-100 monosaccharide units.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it 99pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19,20-24, and 51 are/remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record and those set forth below, because the specification, while being enabling for *treating* or *reducing* bacterial gastrointestinal (GI) infections, specifically *B. coagulans* infections, does not reasonably provide enablement for *preventing* bacterial gastrointestinal infection by any bacterial strain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant argues that amendments to the claim to specify a method of treating and the incorporation of the species group into the claim overcome the rejection; however, Applicant has not amended the claims as stated in the response (see Applicant's Remarks, page 6, ¶ 3).

As stated previously, the claimed recitation of "preventing" GI bacterial infections encompasses the prevention of any and all infections in the gastrointestinal tract, and in every instance. Also, the Examiner has in the previous office action indicated that "the *Clostridium* species" was the focus of the original disclosure and that *B. coagulans* was the demonstrated to reduce bacteria although the scope of the claims was not enabled for all GI bacterial infections.

Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "therapeutic" or "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) – including preventing such disorders as severe diarrhea caused by pathogenic *E.coli* strains which is clearly not recognized in the medical art as being a totally preventable condition.

Applicant has reasonably demonstrated/disclosed that the *B. coagulans*-comprising compound is useful as a therapeutic agent for treating and/or reducing specific gastrointestinal (GI) infections in a human. The amendment to select from *Clostridium perfringens, Clostridium difficile, Clostridium botulinum, Clostridium tributrycum, Clostridium sporogenes, Escherichia coli, Pseudomonas aeruginosa and Staphylococcus aureus* GI bacterial infections are based on *in vitro* test results of pure *B. coagulans* versus pathogen (Specification, page 28, ¶ 1), enabled directly by the *in vivo* studies of the claimed composition versus *Clostridium perfringens,*

Clostridium difficile, Clostridium botulinum, and Staphylococcus aureus. Lacking evidence to the contrary and in light of the direct correlation of the zone-clearance studies *in vitro* to *in vivo* results of inhibiting bacteria against the four species, it is determined that a sufficient number of working examples have been presented to correlate *B. coagulans in vitro* results with the other species (*Clostridium tributrycum, Clostridium sporogenes, Escherichia coli,* and *Pseudomonas aeruginosa*) such that a person of ordinary skill in the art would have a reasonable expectancy of success using *B. coagulans* formulations versus all eight pathogenic bacterial species named above.

The elected species *B. coagulans* and species in the prior art (*L. acidophilus- See 35 USC 102, below*) are the only enabled lactic acid bacterial species and not sufficient to be representative of the breadth of lactic acid bacteria such as those listed in claim 3. In other words, the remaining organisms (the non-elected bacteria) do not have sufficient guidance or sufficient working examples such that one of ordinary skill in the art would not have a reasonable expectation of success to practice the full breadth of the claims, except with *B. coagulans* or *L. acidophilus*.

One of skill in the art would, therefore have to undertake essentially a trial and error process, with no reasonable expectation of success in 1) preventing a GI bacterial infection or 2) practicing the invention with lactic acid bacteria except for *B. coagulans* or *L. acidophilus* provided from the as-filed specification to determine the full scope of the invention as claimed due to: lack of guidance and limited working examples in the specification; nature of the invention; state of the prior art; relative level of skill in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "selected from the group consisting of include" is indefinite and confusing. "Consisting of" is closed language and implies only the specified elements. This is in conflict with "include" which is open language and implies additional elements. It is unclear whether Applicant intends to claim the elements "consisting of" or "including" the species listed. Both are reasonable interpretations and one of skill in the art would not be able to ascertain as to what the subject matter is that Applicant is claiming.

The phrase"20-25 of glucose" is missing the proper unit of measure. It is unclear what units or range is intended. Given the various units of measure (*e.g.* %, gram, g/l, mEq/l, sugar units, etc.) in the originally-filed specification, it is unclear as to which unit Applicant intends to claim.

Claims 13 and 14 recite the limitation "said oligosaccharide" lack clear antecedent basis. Claim 1 does not provide support for the limitations of claims 13 and 14. Claim 13 appears to draw antecedent basis from *bifidogenic oligosaccharide* as claimed in claim 12. Claim 14 appears to draw antecedent basis from the oligosaccharide, FOS, as claimed in claim 13. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In light of applicants arguments/amendments the rejection of claims 12 and 13 based on 35 U.S.C. 102(e) is *withdrawn*.

Applicant has amended the claims to exclude unpatentable alternatives, necessitating further examination on the claims. The rejection, below, is necessitated by Applicant's amendment to the claims.

Claim 1,2,5,7,9, and **11** are rejected under 35 U.S.C. 102(b) as being anticipated by SHACKNAI *et al* (WO 91/15199). Applicant claims treating a bacterial GI infection, including *Clostridium difficile* infection, by the administration to a human an oral electrolyte composition comprising a non-pathogenic lactic acid bacteria.

Shacknai teaches the administration of an oral electrolyte formulation comprising a non-pathogenic lactic acid bacteria. (*e.g. Lactobacillus sp.,* including *L. acidophilus,* but not *B. coagulans*) to treat diarrhea caused by bacterial infection (*e.g. C. difficile*) (page 7, ¶ 2-4; page 8,¶ 3,4,7-9; page 9,¶ 5,6,9).

Shacknai teaches administration to "a human infant", specifically to a child between 2 weeks and 6 years of age (Shacknai, Examples 7 and 14). "At risk for SIDS" does not limit the scope *per* se as all children are *at risk* of SIDS, because SIDS is of an unknown etiology (Dr.Green, page 2, last paragraph).

Shacknai's teaches "a dried cell mass" by lyophilization/dehydration of the formulation (page 7, ¶ 3; page 9, ¶ 10); administering a composition comprising 10^6-10^{12} colony forming units (CFU) (page 11, ¶3; Example 9), including $5x10^9$ CFU (Example 12) anticipating the claims to 10^3-10^{12}, 10^2-10^{10}, and 10^6-10^9 CFU; dose amounts and frequency (Table 4 and Example 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavadini (US PAT 5968569) in view of SHACKNAI (WO 91/15199).

Applicant has amended the claims and argued that a cereal composition does not anticipate an electrolyte formulation. Applicant has not argued the optimization of ranges (e.g.

polymer chain lengths, dosages, etc.), the suitable ingredients (e.g. fructooligosaccharides, etc), or unexpected results.

Cavadini teaches the preparation of food products, including infant cereals (column 2, line 13), which contain probiotic microorganisms including *B. coagulans* (column 3, line 14), and which contain fructooligosaccharides (column 4, line 1) as a soluble fiber component and useful in the treatment and inhibition of intestinal pathogens such as *C. perfringens* and *H. pylori* in humans (see column 1, lines 16-23; see also column 6, lines 50-67). Cavadini further teaches the oral electrolyte formulation, "Bio NAN" (column 1, line 39).

The difference between the teachings of Cavadini and the instant claims is that while Cavadini teaches an oral composition comprising bifidogenic bacteria and while Cavadini teaches oral electrolyte compositions, Cavadini does not directly teach the motivation to combine bifidogenic bacteria and an oral electrolyte solution. Cavadini also does not disclose the composition of the electrolyte composition of "Bio NAN".

Shacknai teaches treating diarrhea, including diarrhea caused by bacterial infection (page 2, ¶ 1), with an orally palatable electrolyte formulation further comprising a bacterial probiotic, including *Lactobacillus sp.* (including *Lactobacillus acidophilus*) (See, Shacknai, Abstract; page 7, ¶ 3,4; page 8, ¶ 7). To further corroborate this motivation to combine, Langhendries *et al* (J. Ped. Gastroent. Nutr.(1995)*21*, 177-181) motivates the benefits of and the combination of a calcium-containing, infant formula electrolyte solution acidified with *Streptococcus thermophilus* and *Lactobacillus helveticus,* the composition further comprising 10^6 viable *Bifidobacterium bifidum* (Langhendries, page 177, methods ¶ 1; page 179, right column, ¶ 2).

It would have been obvious for one of skill in the art to reduce a bacterial infection by either an oral bifidogenic composition or by an oral electrolyte formulation in order to obtain the benefit of increased/sustained clearance rate of the bacteria from the GI tract.

One would have been motivated to use either an oral bifidogenic *B. coagulans*-containing composition or an oral electrolyte formulation because the teachings provide that each composition effectively treats diarrhetic conditions such as those caused by bacteria.

One would have had a reasonable expectation of success in combining the oral bifidogenic bacteria *B. coagulans* composition with an oral electrolyte formulation as other probiotic plus electrolyte combinations are known and each component (*B. coagulans* and oral electrolyte formula) is taught independently to have a beneficial effect in treating GI disorders such as bacterial-induced diarrhea.

The form of a cereal as a flake, powder, slurry, nugget, etc., does not alter the chemical composition of the formulation and there is nothing of record or in the Specification to preclude the use of cereals in an oral electrolyte composition. Combining (dissolving, suspending, etc) the composition of Cavadini with an oral electrolyte solution to treat a bacterial, diarrhetic condition such as that motivated by Shacknai and Langendries would have been *prima facie* obvious to a person of ordinary skill in the art. As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

Applicant's amendment to add the "wherein" clause describing the composition as an *oral electrolyte maintenance composition* has been fully considered; however, lacking functional language in the original disclosure, the Examiner has reasonably interpreted an electrolyte maintenance composition to comprise any electrolyte containing composition. The Examiner also presents that Cavadini (page 1, lines 23-39) describes a commercially available oral formula, under the trademarked name "BIO NAN", which comprises a water-soluble potassium- and sodium-containing electrolyte composition and the probiotics *Streptococcus thermophilus* and *Lactobacillus helveticus*, which is ingested to reduce the number of invasive gastrointestinal fluora.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

In the previous Office action, Examiner required a terminal disclaimer to address the provisional obvious-type double patenting and obvious-type double patenting rejections of **claims 1-11,19-25** and **claims 12-18**. In Applicant's reply, received on June 30, 2006, Applicant responded by amending claims 1, 21, and 22 and canceling claims 20 and 25. Applicant asserted the cancellation of conflicting copending claims in U.S. Pat. Application 11/005897 (Claims 25-35) to respond to the provisional obvious-type double patenting. Furthermore, Applicant asserted filing of a terminal disclaimer to address the obvious-type double patenting; however, as of the drafting of this Office action, no terminal disclaimer has been made of record.

It is acknowledged that the cancellation of the conflicting copending claims has rendered the corresponding need for a terminal disclaimer for the *provisional* rejections on the grounds of nonstatutory obvious-type double patenting (over U.S. Pat. Application 11/005897, claims 25-35) to be moot; however, the request for a terminal disclaimer and the rejection of claims 1-11,19,21-24 and claims 12-18 on the grounds of nonstatutory obvious-type double patenting (versus U.S. PAT. 6461607, claims 13 and 14 and U.S. PAT. 6849256, claims 1-10) is maintained.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references not cited in the prior or present Office Actions considered relevant to the teachings of the present application, have been listed on the PTO-892 form.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0235. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Kosar
Patent Examiner

CECILIA TSANG
SUPERVISORY PATENT EXAMINER